

Remarks

No amendments are made to the claims. Claims 19-27 and 38 are withdrawn.

Restriction Requirement

Applicant affirms election of group I with traverse. While Applicant agrees that the two groups are patentably distinct, Applicant does not agree that searching the two groups places an undue burden on Examiner.

Claim Rejections- 35 U.S.C. § 103

Claims 1-4, 6-18, 28-32, 36 and 37 are erroneously rejected under 35 U.S.C. § 103(a) as allegedly being obvious over Sefton (US 6,262,117) in view of Shefer (US 6,825,161 B2), and further in view of Hawley's Condensed Chemical Dictionary. Claims 1 and 28 are the independent claims, so if they are not obvious, the dependent claims are necessarily non-obvious. As shown herein, Claims 1 and 28 are not *prima facie* obvious. To establish a *prima facie* case of obviousness:

- 1) There must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings.
- 2) The prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP 2143.

Thus, in the present case, to make a *prima facie* case with respect to claims 1 and 28, there must be 1) a suggestion or motivation to modify the teachings of Sefton, 2) a suggestion or motivation to combine Sefton with Shefer, and 3) Sefton and Shefer must teach or suggest all claim limitations.

1. The *prima facie* case fails because there is no suggestion or motivation to modify the teachings of Sefton.

The Office Action alleges that "Sefton teaches that benzoyl peroxide has an inherent problem of decomposing coingredients in topical formulations to thereby cause itching upon application." However, this is part of the background, which points out that this problem was reported in 4,691,956 (Bouillon).

Bouillon teaches that "the group consisting of benzylidenecamphor and its derivatives, 2-phenyl-benzimidazole-5-sulfonic acid and its salts, 2-hydroxybenzophenone and its derivatives, alkyl p-dimethylaminobenzoates, the alkyl radical having from 1 to 12 carbon atoms, the esters of salicyclic acid, the

derivatives of dibenzoylmethane, and the derivatives of cinnamic acid...are the only ones that have proved to exhibit a stabilizing action with respect to benzoyl peroxide" (column 2, lines 17-23). Of these stabilizing sunscreens, alkyl p-dimethylaminobenzoates, the esters of salicylic acid, and the derivatives of cinnamic acid are "a carboxylic acid, or a salt or ester thereof." Thus, if anything, this reference teaches that carboxylic acid esters stabilize benzoyl peroxide rather than being the problematic "decomposing coingredients."

A person of ordinary skill in the art would assume that Sefton was familiar with Bouillon since he cites it. Thus, since Bouillon teaches that some carboxylic acid esters stabilize benzoyl peroxide, and because Bouillon does not teach the combination of azelaic acid and benzoyl peroxide, a person of ordinary skill in the art would know that Sefton's mention of "decomposing coingredients" does not refer to instability problems between azelaic acid and benzoyl peroxide. Sefton does not mention a problem of instability between benzoyl peroxide and azelaic acid. Thus, Sefton would not suggest to a person of ordinary skill that the combination of benzoyl peroxide and azelaic acid would have stability problems. Thus, there is no suggestion or motivation to modify Sefton.

The Office Action alleges that "it would have been obvious" to modify Sefton "because Sefton teaches a suspension of active agents in microparticles is preferable." Sefton states that benzoyl peroxide "may be suspended, preferably in the form of microparticles." This is merely a result of the fact that benzoyl peroxide, which is at a concentration of "preferably from about 2.5 to about 10 percent, by weight, benzoyl peroxide" (Sefton, column 2, lines 32-33), is only sparingly soluble in water (Merck Index Monograph number 01117, enclosed). Thus, at the preferred high concentrations of benzoyl peroxide, although some will be dissolved in the aqueous base, a significant proportion of the benzoyl peroxide will necessarily be suspended. Furthermore, the teaching that the benzoyl peroxide is "preferably in the form of microparticles" is merely an observation that the drug is more efficiently delivered in smaller particles which have a higher surface area to volume ratio. Thus, this does not provide any incentive to further modify the composition, and there is no suggestion or motivation to modify Sefton.

2. The prima facie case fails because there is no suggestion or motivation to combine Sefton with Shefer.

The Office Action alleges that the motivation to combine the references is "because [Shefer] teaches the matrix material provide good barrier properties, low toxicity and irritancy, stability, and high loading capacity for the active agents." However, this is merely an allegation of what Shefer supposedly teaches. There is no explanation as to why a person reading Sefton would be looking for such a matrix material.

3. The *prima facie* case fails because the references do not teach or suggest all the claim limitations.

The Office Action has not explained how Sefton, Shefer, or the references combined teach or suggest the separation of the peroxide and the acid. In the presently claimed compositions, one of the therapeutically active agents is essentially completely contained within in the particles, and one is not.

As explained, Sefton's general allegation of "decomposing coingredients" does not suggest any instability between benzoyl peroxide and the coingredients taught by Sefton. Shefer does teach "nanospheres of encapsulated active ingredients," but it does not teach any instability between benzoyl peroxide and carboxylic acid. Shefer literally lists thousands of compounds that could be "coingredients" with benzoyl peroxide. "The fact that a claimed species or subgenus is encompassed by a prior art genus is not sufficient by itself to establish a *prima facie* case of obviousness." MPEP 2144.08 II citing *In re Baird*, 16 F.3d 380, 382, 29 USPQ2d 1550, 1552 (Fed. Cir. 1994). It follows that the fact a claimed species or subgenus is encompassed by a genus that a particular reference suggests "is not sufficient by itself to establish a *prima facie* case of obviousness." Thus, the thousands of possible coingredients for benzoyl peroxide of Shefer are a genus, and the claimed coingredients are a "subgenus" which is mere fraction of these thousands. This "is not sufficient by itself to establish a *prima facie* case of obviousness." Since nothing else has been provided to support the *prima facie* case, it must fail.

In conclusion, the Office has failed to make a *prima facie* case of obviousness because it has not provided a motivation to modify Sefton, a motivation to combine Sefton with Shefer, and because the two references do not teach or suggest all of the claim limitations. Since the independent claims are not obvious, the dependent claims are not obvious. Thus, the further rejections for those claims will not be discussed.

In light of the points made above and the amendments made to the claims, the Applicants assert that all of the claims meet the statutory requirements for patentability, and therefore respectfully request that the Examiner remove the rejections and pass the application to issue.

Please use Deposit Account 01-0885 for extension of time fees or any other fees or credits relating to this response.

Respectfully submitted,

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